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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,785	04/16/2004	Russell A. Houser	CHFT.003A	9056
43309	7590	10/03/2006	EXAMINER	
SILLS CUMMIS EPSTEIN & GROSS P.C. ONE RIVERFRONT PLAZA IP DEPARTMENT NEWARK, NJ 07102				DOWE, KATHERINE MARIE
ART UNIT		PAPER NUMBER		
		3734		

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

N1

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/825,785	HOUSER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Katherine M. Dowe	3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 April 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 21-24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-15 and 21-24 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/19/2004</u> .   | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 16-20, drawn to a suture with a plurality of sections.
  - II. Claims 1-15 and 21-24, drawn to a method for treating ischemic congestive heart failure.
2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process, such as applying a suture in any medical procedure to close a wound or connect tissue.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. During a telephone conversation with Philip Braginsky on September 5, 2006 a provisional election was made with traverse to prosecute the invention of a suture with a plurality of sections, claims 16-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-15 and 21-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Specification***

6. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

7. The abstract of the disclosure is objected to because the abstract is not informative. Please include the inventive entity of the suture, the invention chosen for examination. Correction is required. See MPEP § 608.01(b).

8. The disclosure is objected to because of the following informalities:

- Paragraph 0001: date for US Patent Application 10/127,714 is incorrect. Date should read "April 23, 2001" instead of "April 23, 2002".

Art Unit: 3734

- Paragraph 0127 refers to the “suture device”, while paragraph 0128 refers to the “shaping suture” and paragraph 0130 refers to the “shaping suture device”. Please use one term for clarity.
- Paragraph 0142: Reference number for the handle should be “132” not “1342”. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 16-20 rejected under 35 U.S.C. 102(b) as being anticipated by Schaller et al. (US 6,613,059). Schaller et al. disclose a suture device (Fig 1), capable of closing an opening in anatomical tissue (Fig 16d; col 3, lines 29-30). The suture device would have a plurality of sections (Fig 1, elements 16/17, 18/19, 2/3, 28/29, and 20; col 3, lines 34-36 and 46-49). The sections may be natural or synthetic (col 6, lines 66-67 and col 7, lines 1-3) and at least one section comprises superelastic or shape memory material, including nitinol (col 7, lines 53-56). Furthermore, Schaller et al. disclose the suture may form a non-circular shape. For example, the suture may be formed in a spiral about a central longitudinal axis, where the suture has a generally conical shape about the longitudinal axis with a decreasing diameter as the radius of curvature of the suture decreases (Fig 5B; col 9, lines 28-32).

11. Claims 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Boebel et al. (US 5,454,834). Boebel et al. disclose a surgical suture material (Fig 1), which is capable of closing an opening in anatomical tissue as is commonly known in the art. The suture has a plurality of sections including a needle (2), thread sections (1), and preformed sections (2,3), which assume a spiral or helical shape (col 8, lines 39-46). The sections may be natural or synthetic (col 7, lines 19-32) and at least one section comprises superelastic or shape memory material, including nitinol (col 7, lines 2-5).

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- US 6,383,204 Ferrera et al.
- US 6,716,234 Grafton
- US 5,645,568 Chervitz et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

kmd



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER